K120357



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510(k) Premarket Notification
ENDOSCOPE REPROCESSOR OER-Mini

DEC 20 2012

# 510(k) Summary

Date Prepared: December 8, 2011

## ❑ Applicant Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
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  Establishment Registration No: 8010047

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- Manufacturer: AIZU OLYMPUS CO., LTD.
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  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No: 9610595

## ❑ Device Identification

- Device Trade Name: ENDOSCOPE REPROCESSOR OER-Mini
- Common Name: Endoscope washer/disinfector
- Class: II
- Regulation Number/Name: 876.1500 Endoscope and accessories
- Product Code: FEB - Accessories, Cleaning, For Endoscope
- Classification Panel: Gastroenterology/Urology
- Performance Standard: None established under Section 514 of FD&C Act.

## ❑ Predicate Device (PD)

- Device Trade Name: ENDOSCOPE REPROCESSOR OER-Pro
- 510(k) Number: K103264
- Manufacturer: AIZU OLYMPUS CO., LTD.

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## Device Description

The OER-Mini Endoscope Reprocessor is an automated endoscope reprocessor intended for cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes, camera heads, light guide cables, miniature light sources and their accessories. Use of the OER-Mini requires detergent and FDA cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Mini and its compatible endoscopes/devices.
Use of the OER-Mini enables the user to perform modified manual cleaning of the endoscope prior to automated cleaning and high-level disinfection in the OER-Mini.

The OER-Mini has been developed to provide an AER that will suit reprocessing of endoscopes in the surgical field. The OER-Mini has a compact and smart-design for table-top use.

The OER-Mini is a one-basin table-top type automatic endoscope reprocessor that performs cleaning, disinfection, rinse to render a high-level disinfected endoscope, device and their accessories. The OER-Mini utilizes an immersion method for cleaning, disinfecting, and rinsing of endoscope/device and its accessory external surfaces, and connectors for endoscope channel cleaning, disinfecting, and rinsing.

The OER-Mini basically can reprocess one device at a time in one-basin, but the immersible certain combination of devices also can be reprocessed simultaneously at a time in a one-basin.

The OER-Mini is capable of automated disinfectant solution dispensing. The external 0.2-micron water filters are bacteria retentive and produce suitable rinse water for reprocessing. Built-in sensors detect fluid levels and temperatures in the reprocessing basin and disinfectant solution tank. If any abnormality/irregularity is detected, an error indicator lights up with an audible alarm and the reprocessing process is a stopped. The device utilizes a touch-panel user interface for program operation and settings. The disinfectant solution is automatically diluted by filtered water until specified quantity in the device. On the other hand, some functions are eliminated in order to realize compact table-top AER;

- No detergent dispensing system. User should manually pour detergent into the device.
- No compressor for air purge.
- No alcohol dispensing system. User should manually pour alcohol into the device.

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The OER-Mini does not have RFID (Radio-Frequency Identification) function. Instead of RFID function, OER-Mini can connect the external-printer (MAJ-1937), which enables to generate hard copy reprocessing record (i.e. operation record, error history etc.). On the reprocessing record, the entered section of user and scope data has been added.

Also, the OER-Mini has a built-in terminal for data communication, which enables the device to output specific information (i.e. operation record, error history, information for determining periodical maintenance timing etc.) to a computer with proprietary software installed for reprocessing record management. It is also possible to alter data and time settings of the OER-Mini from such a computer via this terminal.

- **Indications for Use**

The OER-Mini is intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes, camera heads, light guide cables, miniature light sources, and their accessories. Safe use requires detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Mini and Olympus flexible endoscopes, camera heads, light guide cables, miniature light sources, and their accessories. Use of a detergent or high-level disinfectant/sterilant that has not been validated by Olympus may be ineffective and may damage the OER-Mini components and the endoscopes being reprocessed. Endoscopes must be subject to cleaning by the user prior to reprocessing; however, use of the OER-Mini enables the user to perform modified manual cleaning of the endoscope prior to automated cleaning and high-level disinfection in the OER-Mini.

- **Comparison to Predicate Device**

The OER-Mini is equivalent in indications and operational principles to the OER-Pro. Both devices are intended for high-level disinfection of flexible endoscopes, use an immersion system, flush water/disinfectant to endoscope channels via connectors, and utilize a detergent and FDA-cleared liquid chemical germicide. The major differences from the predicate device are as follows:

- Camera heads, miniature light sources, light guide cables also be added as compatible devices.
- Structure of reprocessing basin is completely different.
- Shorter cleaning time without the ultrasonic cleaning function.
- Does not have a detergent dispense system for detergent cleaning
- Does not have a compressor used for air purge
- Does not have a drain pump used for forced drainage.
- Does not have an alcohol dispense system for alcohol flushing
- Does not have a RFID function

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- **Performance Data**

The OER-Mini has been tested following the requirements in the FDA guidance document titled "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities", issued in August 1993. Test reports provided in this premarket notification include:

Process Parameter Test
The OER-Mini was tested to demonstrate that the device performs as intended. The test results showed that the OER-Mini achieves and maintains the specified physical process parameters, including detection of the defined fault conditions and execution of automatic response/ processing following fault detection.

Validation Testing - Cleaning
The OER-Mini was tested to evaluate its ability to clean its compatible devices in both simulated and in-use conditions. The test results demonstrate that the OER-Mini effectively reduced protein and carbohydrate levels in all sample sites.

Validation Testing – High-Level Disinfection
The OER-Mini was tested to evaluate its ability to high-level disinfect its compatible devices in both simulated and in-use conditions. The simulated use testing demonstrated a 6 $Log_{10}$ reduction of M.terrae at all inoculated sites was achieved after reprocessing in the OER-Mini's disinfection cycle. In-use testing demonstrated no viable microorganisms were recovered from test samples following reprocessing in the OER-Mini.

Validation Testing – Full Cycle
The OER-Mini was tested to evaluate its effectiveness for full cycle reprocessing including both cleaning and disinfection under simulated use conditions. The simulated use testing demonstrated that OER-Mini effectively cleaned and achieved high-level disinfection for its compatible devices.

Simulated-Use Testing – Self-Disinfection
Simulated-use testing was performed to validate self-disinfection of the OER-Mini. Testing demonstrated that a greater than 6 log reduction in M. terrae was achieved for all sample locations after completion of routine reprocessing of endoscopes/devices within the OER-Mini.

Simulated-Use Testing – Water Line Disinfection
The simulated-use testing was performed to validate disinfection of the OER-Mini water line piping which does not contact high-level disinfectant during routine reprocessing. The test result showed that a greater than 6 log reduction in M. terrae was achieved for all sample locations after completion of the water line disinfection procedure.

Toxicological Evaluation of Residues
The safety of residual chemicals remaining on endoscopes/devices after reprocessing in the OER-Mini was evaluated. The test results showed that the OER-Mini reprocessing cycle removes detergent and disinfectant residues to non-toxic levels.

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- **Conclusion**

The information and performance data presented in this premarket notification supports that the OER-Mini is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2012

Olympus Medical Systems Corporation
C/O Ms. Laura Storms-Tyler
Olympus America Incorporated
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K120357
Trade/Device Name: Endoscope Reprocessor Oer-Mini
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: December 7, 2012
Received: December 10, 2012

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K120357

Device Name: ENDOSCOPE REPROCESSOR OER-Mini

Indications For Use:

The OER-Mini is intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes, camera heads, light guide cables, miniature light sources and their accessories. Safe use requires detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Mini and Olympus flexible endoscopes, camera heads, light guide cables, miniature light sources and their accessories. Use of a detergent or high-level disinfectant/sterilant that has not been validated by Olympus may be ineffective and may damage the OER-Mini components and the endoscopes being reprocessed. Endoscopes must be subject to cleaning by the user prior to reprocessing; however, use of the OER-Mini enables the user to perform modified manual cleaning of the endoscope prior to automated cleaning and high-level disinfection in the OER-Mini.

Prescription Use____ AND/OR Over-The-Counter Use_✓_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Elizabeth F. Claverie
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**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** K120357